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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,036	03/22/2006	Osamu Cynshi	CYNSHI 7	4404

1444 7590 07/23/2008

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EXAMINER	
BARTS, SAMUEL A	
ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
07/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,036	CYNSHI ET AL.	
	Examiner	Art Unit	
	Samuel A. Barts	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments filed 04/10/2008 have been fully considered but they are not fully persuasive.

2. Applicant has overcome the 112(1) rejection.

3. Applicant has also overcome the objections to claims 18-31.

4. Applicant's argument with respect to the art rejection is not found convincing.

Applicants submit that the secondary reference of Tsujii fails to demonstrate, by way of data, that the benzofuran derivatives would be useful for treating liver disorders. This argument is not convincing because there is no requirement that the prior art present data to prove an assertion that one skilled in art would reasonably expect to be true. Tsujii clearly states the following:

> ***The object compound (I) and pharmaceutically acceptable salts thereof possess a strong activity to scavenge reactive oxygen species and organic radicals and are useful for the treatment of the diseases caused by reactive oxygen species and organic radicals in human beings or animals and more particularly are useful for the treatment of ischemic heart diseases (e.g. arrhythmia, coronary vasospasm, necrosis of cardiac tissues, myocardial infarction, etc.), ischemic cerebral diseases (e.g. cerebral infarction, dementia, senile dementia, etc.), disorders of the liver, pancrea and kidney and the like.***

This statement is sufficient to clearly show that one skilled in the art would have a reasonable expectation of using the benzofuran compounds to treat liver disorders. Applicant's submission of documents which show that certain compounds were ineffective is not convincing. There is no requirement that the prior art be absolutely certain that the compounds will be effective. Applicant appears to be using a higher standard of evidence which would be more suitable for the FDA. The standard before

the patent office is whether the prior art as whole reasonably suggests that compounds with the claimed structure would have been useful to treat liver disorders. The art as whole does suggest the instant claimed compounds as useful candidates in treating liver disorders.

Applicant has also argued that the compounds of Tsujii are substantially different than the compounds taught by Tamura. This argument is not found convincing since both groups of compounds are benzofuran derivatives. Applicant is reminded that Tsujii is used to show that there is nexus between the treatment of certain diseases. In other words, the references clearly establish a prima facie connection that the compounds that would be useful to treat the diseases disclosed in Tamura would also be useful in treating liver disorders.

The rejection is being maintained.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamura in view of Tsujii. For reasons, see previous office actions and arguments submitted herein.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel A. Barts whose telephone number is 571-272-2870. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel A Barts/
Primary Examiner
Art Unit 1621

sb